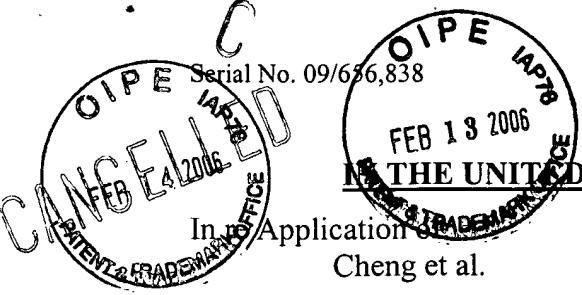


IPW



Attorney Docket No. ITI-P01-008

THE UNITED STATES PATENT AND TRADEMARK OFFICEIn re Application of
Cheng et al.

Serial No: 10/656,838

Filed: September 5, 2003

For: CYCLODEXTRIN-BASED
POLYMERS FOR THERAPEUTICS
DELIVERY

Attorney Docket No.: ITI-P01-008

Art Unit: 1623

Examiner: MAIER, Leigh

Confirmation No.: 8403

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below:

February 8, 2006

Date of Signature
and of Mail Deposit

Christine M. Colbert

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO RESTRICTION REQUIREMENT

Sir:

This amendment is being filed in reply to the outstanding Restriction Requirement, mailed January 26, 2006, in connection with the above application.

Applicants hereby elect Group I, claims 1-20, 27, and 34-35, *with traverse*. The Office requires an election of species; Applicants hereby elect “polymers having cyclodextrins in the backbone,” *with traverse*. Claims 1 (in part), 2, 4, 5-20 (in part), 27 (in part), and 34-35 (in part) read on the species “polymers having cyclodextrins in the backbone.” Applicants request for reconsideration of this restriction requirement for the reasons that follow.

Pursuant to MPEP 803, “If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.” Applicants submit that a

search of the compounds of Group I would necessarily include a search of subject matter directed to methods of treating comprising administration of said compounds or methods for conducting a pharmaceutical business comprising said compounds, *i.e.*, Groups II and III, respectively. As such, a search of the subject matter of Groups II and III would present no additional burden over the search of the subject matter of Group I alone. Accordingly, Applicants request rejoinder of the claims of Groups II and III with those of Group I.

Applicants also point out that according to MPEP 821.04, in cases where claims to a product and a process for making or using the product are presented in the same application, if one or more claims directed to the product are elected and subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim must be rejoined. See *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995). As such, on indication of allowance of product claims of Group I, Applicants note that rejoinder of process claims 21 and 22-26, Groups II and III, respectively, which include all the limitations of claims of Group I, is required as a matter of right.

Regarding the election of species requirement, Applicants note that according to MPEP 802.02 “[t]wo or more inventions are related (*i.e.*, not independent) if they are disclosed as connected in at least one of design (e.g., structure or method of manufacture), operation (e.g., function or method of use), or effect.” Applicants further note that the two species “polymers having cyclodextrins in the backbone” and “polymers not having cyclodextrins in the backbone” share all three of these features: design (both are polymers containing cyclodextrins and therapeutic agents), operation (both are useful in the delivery of therapeutic agents), and effect (the delivery of the therapeutic agents by either species has similar effects, *i.e.*, improved administration of the agent to the subject). Hence, the two species of listed by the Office are shown to be related and thus not independent.

MPEP 808.01(a) states, “Where there is a relationship disclosed between species, such disclosed relation must be discussed and reasons advanced leading to the conclusion that the disclosed relation does not prevent restriction, in order to establish the propriety of the restriction.” In the outstanding Restriction Requirement, the Office has presented no such reasoning, only the conclusory statement “This application contains claims directed to the

following patentably distinct species of the claimed invention..." is offered. Applicants submit that the Office has not met its burden in establishing why restriction is required between "polymers having cyclodextrins in the backbone" and "polymers not having cyclodextrins in the backbone," and the requirement for restriction between these two species is correspondingly improper.

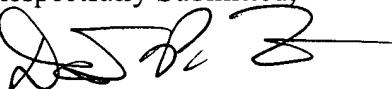
If the election of species is to be maintained, Applicant respectfully request clarification on the basis for the restriction, especially, since Applicants note that a search for cyclodextrin containing polymers would include the subject matter pertaining to both species, and thus not present an additional burden on the Office. Applicants acknowledge that on allowance of the elected species, the Office should expand the scope of examination to encompass the full scope of the corresponding generic claims (MPEP 809.02(a) and 37 CFR 1.141).

The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Date: February 8, 2006

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Respectfully Submitted,



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